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10/086,940	03/01/2002	Sean T. O'Mara	920070.417	6662

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EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/086,940	O'MARA, SEAN T.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-71,73-78,80-113,116 and 119-126* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-71,73-78,80-113,116 and 119-1266* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to amendment filed on November 30, 2007. Examiner acknowledges claims 66-71, 73-78, and 80-113, 116, 119-126 are pending in this application, with claim 112 having been currently amended, claims 119-126 having been newly added, and claims 1-65, 72, 79,114, 115, 117, and 118 having been cancelled

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 66, 67, 71, 73, 74, 78, 90-92, 94, 95, 112, 113, and 116 are rejected under 35 U.S.C. 102(b) as being anticipated by Parker (5,873,362).

As to Claims 66, 73, 90-92, Parker discloses a method comprising: inserting an intubation-tube placement device (73) secured to an intubation tube (10), into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator (54) device coupled to the intubation-tube placement device (via the cooperative interaction of elements 73 and 10); forcing the intubation-tube placement device through the patient's vocal cords (88, using the distal end 18 of the intubation

tube 10) and axially sliding the intubation tube (10) along the intubation-tube placement device (73) such that the intubation tube (10) follows the intubation-tube placement device through the patient's vocal cords. (Figures 4A and 4B). As seen in Figure 4B, the tactile-accentuator (54) guides the intubation tube (10) along the cartilaginous rings (90). In regards to claim 73, the exploratory portion (74) is shaped to prevent the intubation-tube placement device from perforating an internal body structure during insertion into the patient's oral cavity. In regards to claims 90-92, Parker discloses the placement device (73) may be removed from the intubation tube (10). (Column 5, Lines 15-20).

As to Claims 67, 74, Parker discloses the operation of the intubation tube placement device may additionally encompass the use of a light source (100). (Column 5, Lines 20-24).

As to Claims 71, 78, Parker discloses the forcing of the intubation-tube placement device through the patient's vocal cords, comprises: applying axial pressure along the intubation-tube placement device such that the intubation-tube placement device moves into the patient's trachea. (Column 5, Lines 2-20).

As to Claim 94, Parker discloses detecting the cartilaginous rings of the trachea via at least one tactile-accentuator (54) device coupled to the intubation-tube placement device (via the cooperative interaction of elements 73 and 10). (Figures 4A and 4B). As seen in Figure 4B, the tactile-accentuator (54) guides the intubation tube (10) along the cartilaginous rings (90).

As to Claim 95, Parker discloses a plurality of ventilation holes (120) along the wall in the portion of the endotracheal tube (10) that follows the endotracheal placement device. (Column 5, Lines 47-57).

As to Claim 112, Parker discloses a intubation tube (10), comprising: a first end (16) having a first opening; and a second end (18) configured to pass through a set of vocal cords (88); a plurality of openings (12) on a portion of the wall of the intubation tube (10) adjacent to the second end (18) of the intubation tube. (Figure 1, 4A, and 4B).

As to Claims 113 and 116, Parker discloses a tip (58) of the second end (18) of the intubation tube is rounded in shape and tapered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 68-70, 75-77, and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker (5,873,362) in view of Flam (5,607,386).

As to Claims 68, 75, and 93, Parker discloses the recited method but does not expressly disclose the suctioning of materials. However, at the time the invention was made, the use of suctioning materials formed within the intubation-tube placement device was known. Specifically, Flam, in a method of inserting an intubation-tube

placement device, teaches suctioning materials from a vicinity of the patient's vocal cords via a suction tube formed by the intubation-tube placement device (col.7, lines 50-59) for the purpose of clearing mucous and debris from a patient's respiratory tract. Flam also discloses the use of the suction tube for insufflating a patient for providing breathable gas to a patient during the intubation process. Therefore, it would have been obvious to modify the intubation-tube placement device of Parker to provide a suction tube for suctioning materials from a vicinity of a patient's vocal cords because it would have provided a means for clearing mucous and debris from a patient's respiratory tract as well as provided a means for delivering breathable gas to a patient during the intubation process as taught by Flam.

As to Claims 69 and 76, Parker as modified by Flam teaches the intubation-tube placement device forming a hollow tube (suction lumen extends entire length of device as disclosed at col.7, lines 50-59 of Flam).

As to Claims 70 and 77, Flam teaches the suction tube formed by the intubation tube placement device comprises: the intubation-tube placement device forming a hollow tube (i.e. note insufflation and suction lumen that extends entire length of device); an anti-perforation device having a trailing portion (e.g. adjacent handle #13) and an exploratory portion; a channel (col.7, lines 50-59) between the trailing portion and the exploratory portion of said anti-perforation device, and the trailing portion coupled to said intubation-tube placement device such that the channel substantially aligns with hollow tube.

6. Claims 80-88, 96-99, 109-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker ('362) in view of Flam ('386), and further in view of Slanetz, Jr. ('091).

As to Claims 80, 88, 96, 98, 109, 110, Parker discloses an intubating apparatus having a intubation placement device (10) and a retention device (73), yet does not expressly disclose the particulars of the intubation placement device nor the anti-perforation device. However, at the time the invention was made the structural particulars of the intubation placement device and the anti-perforation device were known. Specifically, Flam ('386) teaches an apparatus comprising: an intubation tube placement device (10); and an anti-perforation device (21,22) coupled to said intubation tube placement device for assisting in the placement of the intubating member into the patient's trachea. However, the system of Parker as modified by Flam does not expressly disclose the anti-perforation device having an exploratory portion shaped to prevent the anti-perforation device from perforating an internal body structure during insertion. Slanetz, Jr. teaches an anti-perforation device (12) having an exploratory portion (25) shaped to prevent the anti-perforation device from perforating an internal body structure for the purpose of preventing the rupture (i.e. perforation) of a duct by signaling a control unit of an area of greatest pressure being exerted on the exploratory portion (col.2, lines 43-47 and lines 62-65). Therefore, it would have been obvious to modify system of Parker/ Flam to include an exploratory portion of the anti-perforation device shaped to prevent perforation of an internal body structure during insertion, as taught by Slanetz, Jr. to provided a means for preventing the rupture of a duct by

signaling a control unit of an area of greatest pressure being exerted on the exploratory portion.

As to Claims 81, 82, 97, 111, Flam (figs.2,3,5,7) teaches an intubation tube (24) secured to the intubation tube placement device (12), the intubation tube placement device being internal to the intubation tube and a retaining device comprising a rubber stopper (23) having a hole through which the intubation tube placement device (12) extends, the retaining device being in contact with said intubation tube.

As to Claim 83, 99, Flam (col.7, lines 50-59) discloses said intubation tube placement device forms a hollow tube (i.e. note insufflation and suction lumen that extends entire length of device); said anti-perforation device having a trailing portion (e.g. adjacent handle #13) and an exploratory portion (e.g. adjacent tip of device #21) and a channel (col.7, lines 50-59) between the trailing portion and the exploratory portion of said anti-perforation device; and the trailing portion coupled to said intubation tube placement device such that the channel aligns with the hollow tube.

As to Claim 84, Parker discloses the operation of the intubation tube placement device may additionally encompass the use of a light source (100). (Column 5, Lines 20-24). In addition, Flam discloses a fiber optic device includes a light source (col.7, line 49).

As to Claims 85, 86, 87, 100, Flam discloses the intubation placement device (12) is a medical device made of a malleable material. (Column 4, Lines 40-65).

As to Claim 89, 101, 102, 104, 105, Parker discloses at least one tactile-accentuator (54) device coupled to the intubation-tube placement device for detecting

the cartilaginous rings of the trachea (via the cooperative interaction of elements 73 and 10). (Figures 4A and 4B). As seen in Figure 4B, the tactile-accentuator (54) guides the intubation tube (10) along the cartilaginous rings (90).

As to Claim 103, 106, 107, Parker discloses a plurality of ventilation holes (120) along the wall in the portion of the endotracheal tube (10) that follows the endotracheal placement device. (Column 5, Lines 47-57).

As to Claim 108, Parker discloses an inflatable cuff (24) and a plurality of ventilation holes (120) along the wall in the portion of the endotracheal tube (10) that follows the endotracheal placement device. (Column 5, Lines 47-57).

7. Claims 119-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker ('362) in view of Flam ('386), Slanetz, Jr. ('091), and further in view of Evans et al. (5,250,033).

As to Claims 119-121, 123, and 124, the system of Parker/Flam/Slanetz discloses the recited intubation tube device with the exception of the means for removable securing including a detactable portion of the intubation tube having a perforated border. However, at the time the invention was made the use of a detactable portion of the intubation tube having a perforated border was known. Specifically, Evans teaches the detachment of the adapter and the tube by perforated edge (30) for the purpose of enabling the proper placement of the device to the targeted region (Figure 2, Column 3, Lines 32-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system

of Parker/Flam/Slanetz to include a removable portion of the adapter, as taught by Evans to ensure proper placement of the device within the body and to enable easy removable of the guide from the intubation device. Regarding the perforated limitation, Applicant is advised that the recitation of perforation is directed to a process. Applicant is reminded patentable weight is only given to the end product in apparatus/product claims.

As to Claim 122, 125, and 126, the system of Parker/Flam/Slanetz discloses the recited intubation tube device with the exception of the means for removable securing including a detactable portion of the intubation tube having a perforated border. However, at the time the invention was made the use of a detactable portion of the intubation tube having a perforated border was known. Specifically, Evans teaches the detachment of the adapter and the tube by perforated edge (30) for the purpose of enabling the proper placement of the device to the targeted region (Figure 2, Column 3, Lines 32-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Parker/Flam/Slanetz to include a removable portion of the adapter, as taught by Evans to ensure proper placement of the device within the body and to enable easy removable of the guide from the intubation device.

Response to Arguments

8. Applicant's arguments filed November 30, 2007 have been fully considered but they are not persuasive. Applicant asserts the prior art made of record does not teach or

fairly suggest a tactile-accentuator coupled to the intubation tube placement guide. However, Examiner respectfully disagrees. Applicant's claim limitations simply recite the tactile- accentuator device is coupled to the intubation tube placement guide; yet, these claim limitations to not recite how the structural orientation of the coupling mechanism. Parker discloses a intubation tube (10) that is operatively coupled to the intubation tube placement device (73). (Figure 4A). Inherently, this operative coupling of these elements meets the claims as Applicant has not expressly recited the integral nature of the intubation tube placement device and the tactile- accentuator. Further Applicant's assertions of the tactile- accentuator (54) of Parker to be incapable of detecting the cartilaginous rings is improper. As shown in Figure 4B, the tactile-accentuator is used to determine the proper placement of the device within the trachea (Column 5, Lines 40-48). Thus in light of the aforementioned reasoning the rejection of the claims has been maintained.

Response to Amendment

9. The declaration filed on April 30, 2007 under 37 CFR 1.131 is sufficient to overcome the Bonutti reference.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

Annette F Dixon
Examiner
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